

REMARKS

In response to the above-identified Office Action (“Action”), Applicant seeks reconsideration thereof. In this response, Claims 1 and 2 have been amended, no claims have been cancelled and no claims have been added. Accordingly, claims 1-20 are pending.

The instant application is directed to a microfluidic device manufactured by binding a sensing substrate including a sensing electrode, an electrode interconnect, and an electrode pad formed on a top surface of the sensing substrate, the sensing electrode, electrode interconnect and electrode pad having a planar structure, with a channel substrate including at least two fluid inlet ports, a chamber, and a channel, the chamber and the channel formed on a surface of the channel substrate, wherein the sensing substrate and channel substrate are bound at each channel and chamber to form a capillary channel, and an external pump, the capillary channel and the external pump control a flow of a first fluid and a second fluid wherein a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by the external pump.

I. Amendments to the Claims

Applicant respectfully submits herewith amendments to Claims 1 and 2. Claim 1 is amended to clarify that the sensing substrate and channel substrate are bound at each channel and chamber to form a capillary channel and an external pump is further claimed such that the capillary channel and the external pump control a flow of a first fluid and a second fluid wherein a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by the external pump. Support for the amendment to Claim 1 may be found, for example, on page 11, lines 2-4, lines 18-34; page 12, lines 12-27; page 13, lines 1-34; page 14, lines 1-14; page 15, lines 16-34.

Claim 2 is amended to clarify that a first channel path from one of the fluid inlet ports and a second channel path from the other fluid inlet port intersect at a site of designation such that the first fluid flows along the first channel path up to the site of designation by capillary force, and the second fluid flows along the second channel path up to the site of designation and is forced to push out the first fluid that stays at the site of designation for fluid exchange. Support for the amendment to Claim 2 may be found, for example, on page 9, lines 8-21; Figure 4. Applicant

respectfully requests the Examiner's consideration and entry of the attached amendments to Claims 1 and 2.

II. Claims Rejections Under 35 U.S.C. §112

In the outstanding Action, the Examiner rejects Claims 1-10 under 35 U.S.C. §112, second paragraph as being unclear for failing to particularly point out and distinctly claim the subject matter Applicant regards as the invention. In particular, the Examiner alleges Claim 1 does not set forth the structural cooperation between the sensing substrate and the channel substrate and Claim 2 does not clearly recite the structural elements that provide the channel path up to a site of designation. Applicant respectfully submits the previous amendment to Claim 1, namely, that the sensing substrate and the channel substrate are abound at each channel and chamber to prevent leakage of the injected fluids sets forth the structural relationship between the sensing substrate and the channel substrate. Nevertheless, Applicant further submits herewith amendments to Claims 1 and 2 in which the features noted by the Examiner have been clarified. In particular, Applicant has amended Claim 1 to clarify that "the sensing substrate and channel substrate are bound at each channel and chamber to form a capillary channel, and an external pump, wherein the capillary channel and the external pump control a flow of a first fluid and a second fluid such that a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by the external pump." As is described in Applicant's specification, an external pump in the case of forced fluid flow and the capillary channel in the case of natural capillary flow may be provided for controlling the flow of the fluids within the device. See for example, Application, page 11, lines 1-16, 32-34; page 12, lines 17-27; page 14, lines 5-14.

As previously discussed, Claim 2 is amended to clarify that a first channel path from one of the fluid inlet ports and a second channel path from the other fluid inlet port intersect at a site of designation such that the first fluid flows along the first channel path up to the site of designation by capillary force, and the second fluid flows along the second channel path up to the site of designation and is forced to push out the first fluid that stays at the site of designation for fluid exchange. See, for example, Application, page 9, lines 8-21; Figure 4. Applicant respectfully submits amended Claim 2 clarifies that the intersection of the channel paths extending from the fluid inlet ports intersect at the predetermined site allows the second fluid

flowing through the second channel path to push out the first fluid found at the predetermined site.

In view of the foregoing, Applicant respectfully submits, Claims 1-10 are in compliance with 35 U.S.C. §112 and respectfully requests withdrawal of the rejection to these claims.

III. Claims Rejected Under 35 U.S.C. §102(b)

The Examiner rejects Claims 1-4 under 35 U.S.C. 102(b) as being anticipated by PG PUB 2004/0007275 issued to Hui Liu et. al. ("Hui"). Applicant respectfully traverses the rejection for at least the following reasons.

To anticipate a claim, the relied upon reference must disclose every limitation of the claim. In response to Applicant's previous arguments that Hui fails to teach at least two fluid inlet ports and an external pump wherein "a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by an external pump" the Examiner alleges in response to Applicant's previous arguments that Hui teaches at least two fluid inlet ports, that an external pump is not positively claimed and in any event, Hui teaches such a pump. See Action, page 2, paragraph 2; page 4, paragraph 6. In addition, the Examiner alleges the recitation of fluid flow by capillary force and an external pump is functional and therefore must be recited in "means" form to be given patentable weight and "supported by recitation in the claim of sufficient structure to warrant the presence of the functional language." See Action, page 2, paragraph 2. Applicant respectfully disagrees with the Examiner's determination.

As an initial matter, Applicant believes the Examiner misstates the law in requiring Applicant to include "means" language in the claim supported by a recitation in the claim of a corresponding structure. See Action, page 2. Instead, Applicant believes such language must be supported by structural language found within the specification, not the claims. In any event, Applicant does not believe Claim 1 provides a functional recitation as alleged by the Examiner. As previously pointed out, the fluid flow may be controlled by the presence of an external pump and/or the capillary channels. Amended Claim 1 clearly recites that structures such as the "external pump" and "capillary channel" are part of the claim and facilitate the claimed fluid flow. Accordingly, the limitations recited in amended Claim 1 are not functional.

In regard to the claimed “at least two fluid inlet ports...a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by an external pump”, the Examiner again fails to point out wherein within Hui these elements are expressly recited. The Examiner alleges Hui teaches two inlet ports 1111, 1116 and two controlled fluids being pumped [0029] and that the while the “controlled fluids” are driven by pump, the other fluids flow due to natural forces citing to Hui Claim 2 and paragraphs [0017], [0020] and [0039].

Applicant has reviewed these portions of Hui and fails to discern where it is taught that a first fluid from a first fluid inlet port flows by natural capillary force while a second fluid from a second fluid inlet port flows by an external pump. In particular, paragraph [0020] describes an embodiment of a close-open fluidic valve in which the flow of a fluid from inlet port 325 along channel 310 to outlet port 330 is controlled by the application of pressure. See Hui, paragraph [0020]. Thus, although this portion teaches a single inlet port and flow of a single fluid, Applicant is unable to discern where a second fluid inlet port, a second fluid and an external pump are described. Similarly, Claim 2 and paragraphs [0017] and [0039] describe forces involved in moving the fluid within a channel however fail to expressly or implicitly teach both a first fluid from a first fluid inlet port which flows by natural capillary force and a second fluid from a second fluid inlet port which flows by an external pump.

Moreover, contrary to the Examiner’s allegations, Hui teaches an internal pump. Hui teaches that after the user loads the chambers and the PCR reaction is completed, the pump heater is activated and as a result of the localized heating of the pump chamber 105, air in the pump chamber expands acting as a forward pump. See Hui, paragraph [0016]. This pressurized air from the air pump chamber 105 then moves the buffer in chamber 110 into chamber 115 to mix with the PCR product and further to chamber 120 for hybridization. See Hui, paragraph [0016]. Accordingly, Hui not only teaches an internal pump but that the same pump forces the flow of both the sample and reagents. Thus, an external pump to force flow of a second fluid and flow of a first fluid by natural capillary force is not taught by Hui.

For at least the foregoing reasons, the Examiner has failed to set forth, and Applicant is unable to discern wherein within Hui at least the elements of a channel substrate including at least two fluid inlet ports wherein a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by an

external pump are taught. Since Hui fails to teach all the elements of Claim 1, anticipation may not be found. For at least the foregoing reasons, Applicant respectfully requests withdrawal of the rejection of Claim 1 under 35 U.S.C. §102.

Claims 2-4 depend from Claim 1 and incorporate the limitations thereof. Thus, at least for the reasons discussed above in regard to Claim 1, Hui fails to teach or suggest all the elements of Claims 2-4. Since each element of Claims 2-4 is not taught by Hui, anticipation may not be found. For at least the foregoing reasons, Applicant respectfully requests withdrawal of the rejection of Claims 2-4 under 35 U.S.C. §102.

IV. Claims Rejected Under 35 U.S.C. §103(a)

A. The Examiner rejects Claims 5-9 under 35 U.S.C. 103(a) as being obvious over Hui in view of PG PUB 2002/0150683 issued to Troian et al. ("Troian"). Applicant respectfully traverses this rejection for at least the following reasons.

To render a claim obvious, the relied upon references must teach or suggest every limitation of the claim such that the invention as a whole would have been obvious at the time the invention was made to one skilled in the art. Claims 5-9 depend from Claim 1 and incorporate the limitations thereof. Thus, for at least the reasons discussed above in regard to Claim 1, Hui fails to teach or suggest a microfluidic device having a channel substrate including at least two fluid inlet ports wherein a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by an external pump. The Examiner has not pointed to, and Applicant is unable to discern any portion of Troian teaching these elements. Since the relied upon references fail to teach or suggest all the elements of Claims 5-9, a *prima facie* case of obviousness may not be established. For at least the foregoing reasons, Applicant respectfully requests withdrawal of the rejection of Claims 5-9 under 35 U.S.C. §103.

B. The Examiner rejects Claims 10-14 and 20 under 35 U.S.C. 103(a) as being obvious over Hui in view of PG PUB 2003/0190608 issued to Blackburn et al. ("Blackburn"). Applicants respectfully traverse this rejection for at least the following reasons.

In regard to Claim 10, Claim 10 depends from Claim 1 and incorporates the limitations thereof. Thus, for at least the reasons discussed above in regard to Claim 1, Hui fails to teach or suggest a microfluidic device having a channel substrate including at least two fluid inlet ports

wherein a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by an external pump. The Examiner has not pointed to, and Applicant is unable to discern any portion of Blackburn teaching these elements. Since the relied upon references fail to teach or suggest all the elements of Claim 10, a *prima facie* case of obviousness may not be established. For at least the foregoing reasons, Applicant respectfully requests withdrawal of the rejection of Claim 10 under 35 U.S.C. §103.

Independent Claim 11, similar to Claim 1, is directed to a microfluidic device having a channel substrate including at least two fluid inlet ports wherein a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by an external pump.

The Examiner alleges the element of “an external pump” is not positively claimed and is therefore not given patentable weight. Applicant respectfully disagrees with the Examiner’s determination. Claim 11 clearly states the fluid flows by the action of “an external pump.” It is unclear to Applicant how such an explicit recitation of an element cannot be considered part of the claim. Moreover, as is clear from the specification, exchange of fluids is accomplished by the forced flow of the second fluid to the site of designation by the external pump. See Application, page 3, lines 17-20. Thus, if the external pump were not part of the invention, the purpose of the invention (a microfluidic device enabling fluid exchange) could not be accomplished. For at least these reasons, the “external pump” should be given patentable weight. If the Examiner chooses to maintain her position, Applicant respectfully requests clarification as to what language the Applicant must use for an element to be “positively claimed.”

In the absence of such clarification, Applicant respectfully submits the “external pump” is part of the claims thus, at least for the reasons discussed above in regard to Claim 1, Hui fails to teach or suggest a microfluidic device having a channel substrate including at least two fluid inlet ports wherein a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by an external pump. The Examiner has not pointed to, and Applicant is unable to discern any portion of Blackburn teaching these elements. Since the relied upon references fail to teach or suggest all the elements of Claim 11, a *prima facie* case of obviousness may not be established. For at least the foregoing reasons, Applicant respectfully requests withdrawal of the rejection of Claim 11 under 35 U.S.C. §103.

In regard to Claims 12-14 and 20, these claims depend from Claim 11 and incorporate the limitations thereof. Thus, for at least the reasons discussed above in regard to Claim 11, neither Hui nor Blackburn teach or suggest a microfluidic device having a channel substrate including at least two fluid inlet ports wherein a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by an external pump. Since the relied upon references fail to teach or suggest all the elements of Claims 12-14 and 20, a *prima facie* case of obviousness may not be established. For at least the foregoing reasons, Applicant respectfully requests withdrawal of the rejection of Claims 12-14 and 20 under 35 U.S.C. §103.

C. The Examiner rejects Claims 15-19 under 35 U.S.C. 103(a) as being obvious over Hui in view of Blackburn and further in view of Troian. Applicants respectfully traverse this rejection for at least the following reasons.

Claims 15-17 and 19 depend from Claim 11 and Claim 18 depends from Claim 1 and incorporate the limitations thereof. Thus, for at least the reasons discussed above in regard to Claims 1 and 11, neither Hui, Blackburn nor Troian teach or suggest a microfluidic device having a channel substrate including at least two fluid inlet ports wherein a first fluid injected via one of the fluid inlet ports flows by natural capillary force, and a second fluid injected via another fluid inlet port flows by an external pump. Since the relied upon references fail to teach or suggest all the elements of Claims 15-19, a *prima facie* case of obviousness may not be established. For at least the foregoing reasons, Applicant respectfully requests withdrawal of the rejection of Claims 15-19 under 35 U.S.C. §103.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207-3800.

Respectfully submitted,

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Jean Syoboda

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